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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,954	07/03/2003	Mok-Kun Jeong	239870US2	3522

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EXAMINER
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JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/611,954	Applicant(s) JEONG ET AL.	
	Examiner Jaworski Francis J.	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8-27-04(IDS).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6 and 9 is/are rejected.
- 7) ☒ Claim(s) 2,3,5,7,8 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08272004</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(Parenthesized claim number(s) pertain to the claim or claims towards which the immediately preceding rejection statement is directed.)

Claims 1, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Von Behren et al (US6558324).

Von Behren et al is directed to a tissue elastographic imaging system which in one embodiment uses intensity or brightness-based speckle tracking algorithms to determine a pixel displacement. Tissue strain is a differential of such displacement, and so sequential frames are used to obtain strain values as a pixel displacement differential  $D(i,j,k)$ . Tissue elasticity  $E(i,j,k)$  is then calculated as the pixel displacement

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differential referenced to local average displacement value hence is a relative expression self-referenced to the tissue.

As an anticipatory reading, Von Behren et al teaches structure and steps for applying **ultrasonic** vibrations to the tissue (via 138, 140, 142, see col. 5 line 24 characterizing as 'vibrations'),

[ The claim language does not distinguish the vibration application step or source as apart from the ultrasound imaging frame process/structure and does not indicate how the speckle brightness variation relates to the applied vibration and medium elasticity vibration response as opposed to the ultrasound vibration needed to extract the resulting brightness pattern changes and express them as a calculated result]

or in the alternative, applying a cyclic strain-inducing compression to the tissue (see col. 7 lines 6 – 32)

[ To suffice as a vibration under broadest interpretation, one need only cyclically shake or jiggle so as to set into motion about opposite directions with respect to an equilibrium point. No further specificity is set forth in the base claims regarding this feature.]

acquiring two or more successive ultrasound image frames (cols. 7-8 bridging; col. 9 – 10 bridging, structure 123),

estimating a spatial variation of speckle brightness pattern (i.e its displacement) in successive frames (see col. 8 line 52 – col. 9 line 12 and structure 124) to produce displacement differential set  $D(l,j,k)$ , and

measuring elasticity of the tissue medium by converting the displacement set D to E (i,j,k) or the locally referenced elasticity value set as per fig. 2 and structure 125, and providing a colorized display overlay as the output of such measurement. via structures 122, 180. (Claims 1, 6).

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinberg (US5839441, of record with the IDS filed August 27, 2004).

Steinberg is directed to disparity imaging based upon speckle pattern changes between successive ultrasound image frames as an index of tissue density of tumors or foreign object presence within tissue.

Read against the method and structure of the base claims, Steinberg:

Applies a cyclic vibration stimulus (in the disparity imaging case this is cyclic probe compression, see para 8 lines 37 – 39; in the tissue density case the cyclicity is by shallow breathing which constitutes a vibration under the above definition),

Acquires successive ultrasound B-mode frames,

correlates speckle brightness variation between the images, , and provides a disparity map measure of dense tissue e.g. tumor nodules within soft tissue, essentially an elasticity-based display presentation, see col. 2 lines 46 – 66.(Claims 1, 6).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Behren et al in view of Ophir et al (US5474070).

For purposes of this rejection, the above anticipatory argument generally applies but is modified regarding 'applying vibrations (Claim 1)/vibrator(Claim 6)' in acknowledgment of the fact that since some practitioners of tissue elasticity measurements use quasi-static compression as opposed to cyclic vibration for the reason that an external vibratory driver creates non-standardizations (What is the actual applied force magnitude at the tissue boundary) and artifact error (how good is the driver at applying force in a pure axial compression direction and what is the actual waveshape being delivered as the tissue mechanically backloads the driver?), Ophir et al being one such practitioner group, see col. 3 line 59 – col. 4 line 4, it might then not **inherently** follow in the anticipatory sense that Von Behren et al use a vibratory drive as opposed to another type of compression cycling mode. However since Von Behren et al is acting during a continuum feed of image frames within processor 120, it would have been logical to provide a continuous vibrational type drive as acknowledged in Ophir et al col. 3 lines 24 – 38, even though Ophir et al never use the term thereafter to characterize their Fig. 6 device..

Claims 1-6 are further rejected under 35 U.S.C. 103(a) as being unpatentable over Steinberg as applied to claim 1 above, and further in view of Ophir et al, for reasons paralleling the above, namely that since Steinberg also operates on a continuum of images, although he does not state that a vibration source is used it would have been obvious to provide same to produce data at the image update rate..

Ophir et al additionally notes the equivalence of internal (pulsations/heart beat) to external vibration sources col. 3 lines 14 – 18. (Claims 1, 6).

Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Behren et al alone or further in view of Ophir et al as applied to claim 1 above, and further in view of Chen et al (US5876342)..

The former are applied as above, but Von Behren alone or as supplemented by Ophir et al do not teach specific calculation of pixel maximum and minimum brightnesses together with absolute difference values.

Chen et al is not directed to tissue elasticity measurements but rather to the registration of ultrasound scan volume cubages, ,i.e. the stacking of 2D slices into a three-dimensional storage where for operator flexibility an untethered or free-hand 2D transducer is being used and therefore uneven in-plane and out-of-plane transducer movements are occurring, against which the obtained images must be correctly registered. Chen et al does contain a speckle tracking algorithm for in-plane motion or displacement between successive frames. Chen et al in effect provides an equivalent interframe displacement measuring sub-process and substructure for determining

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'where did each pixel displace to recently?' and the fact that in Chen et al the calculated displacement associates with a vectored transducer movement and not tissue movement due to vibration nor does it integrate towards an elasticity measurement does not negative its basic algorithmic equivalence.

Specifically, since in Von Behren et al col. 9 lines 2 – 7 the proposal is made that interframe motion or displacement may be determined by a cost function which is a generic expression for a minimum-sum-and-difference (MSAD) algorithm for the power exponent  $n = 1$  case, it would have been obvious in view of Chen et al col. 4 lines 25 – 27 and 42 – 45 that when using an MSAD algorithm in Von Behren et al to perform speckle correlation between successive ultrasound scan frames, [as opposed to the mutual alternative least-squares algorithm – Von behren et al col. 9 lines 8-9 vs Chen et al col. 4 lines col. 4 lines 61-67], one would include in the MSAD in-plane calculations of col. 14 lines 5 – 56, the quality factor  $QF(i)$  which needs be determined as in the out-of-plane case, namely histogram stratification of pixel brightnesses over all the component frames must be made as per cols. 9 – 10 and then factor into the sum-and-difference calculations, in the course of which the max/min and absolute difference values among pixels would be calculated. (claims 4, 9).

Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinberg alone or further in view of Ophir et al as applied to claim 1 above, and further in view of Chen et al, for reasons paralleling the application of Chen et al above. Namely, since Steinberg in col. 5 is analogously detailing processes for correlating speckle window displacements via correlation or means-squared differencing, one

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would look to chen et al for specifics of interframe speckle correlation determination of displacements, and the applicability of Chen et al as detailed immediately above applies here.(Claims 4, 9).

### ***Allowable Subject Matter***

Claims 2 – 3, 5, 7 - 8 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Patentability Assessment**

Speckle correlation tracking had been used earlier in the ultrasound field to determine blood flow alternative to Doppler frequency shift measurement, and carries forward into elastographic measurement as a sub-process within the measurement that is tasked with determining tissue displacement in order to calculate strain. The Von Behren et al-based rejection proposes that the spatial variation of speckle brightness when calculated by an algorithmic process is effectively part of an elastographic measurement which occurs between image frames and which is overall readable against the claims rejected, either as an anticipatory document or enhanced by a secondary teaching regarding the 'vibration' issue.

Speckle tracking is analogously used as a sub-process in the context of non-elastographic inter-frame processing such as image registry/therapy alignment as a

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general solution to 'where did that tissue region locally move to recently?' and therefore Chen et al is used in supplement to Von Behren et al for specific computation features.

(Also see Hill et al (GB2279743A, page 1 line 31 – page 2 line 17 cited as background only.).

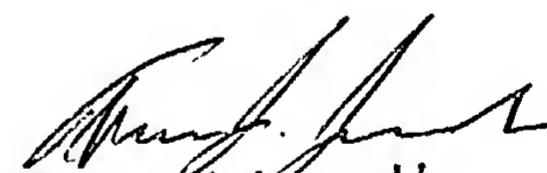
The Steinberg patent teaches what is tantamount to an elastographic measurement which is based upon variation in speckle brightness at a given pixel location in a series of image frames.

Patentability is acknowledged to reside in claims 6 and 7 because they are sufficiently specific to distinguish applicants' computation process and system structure in relation to the more generic speckle tracking of tissue displacement and the particularized disparity mapping of Steinberg, and without regards to more generic patentable distinctions which may be present..

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

FJJ:fjj

09152004

  
Francis J. Jaworski  
Primary Examiner